

**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

IN RE: SPECTRUM PHARMACEUTICALS
INC., SECURITIES LITIGATION,

Case No. 2:13-cv-00433-LDG (CWH)
Base File

ORDER

Lead plaintiff Arkansas Teacher Retirement System has filed a Consolidated Amended Class Action Complaint (#103) against defendants Spectrum Pharmaceuticals, Inc., Rajesh C. Shrotriya, Brett L. Scott, and Joseph Kenneth Keller. The defendants move to dismiss the complaint (#108), arguing that it fails to plead the pleading requirements of Federal Rules of Civil Procedure 8(a), 9(b), and 12(b)(6), and the heightened pleading standards of the Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4(b). The plaintiff has opposed the motion (#114). Having considered the arguments of the parties, the pleadings and the papers, the Court will deny the motion.

Motion to Dismiss

A motion to dismiss brought pursuant to Fed. R. Civ. P. 12(b)(6) challenges whether the plaintiff's complaint states "a claim upon which relief can be granted." In ruling upon this motion, the court is governed by the relaxed requirement of Rule 8(a)(2) that the complaint need contain only "a short and plain statement of the claim showing that the

1 pleader is entitled to relief.” As summarized by the Supreme Court, a plaintiff must allege
2 sufficient factual matter, accepted as true, “to state a claim to relief that is plausible on its
3 face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Nevertheless, while a
4 complaint “does not need detailed factual allegations, a plaintiff’s obligation to provide the
5 ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a
6 formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555 (citations
7 omitted). In deciding whether the factual allegations state a claim, the court accepts those
8 allegations as true, as “Rule 12(b)(6) does not countenance . . . dismissals based on a
9 judge’s disbelief of a complaint’s factual allegations.” *Neitzke v. Williams*, 490 U.S. 319,
10 327 (1989). Further, the court “construe[s] the pleadings in the light most favorable to the
11 nonmoving party.” *Outdoor Media Group, Inc. v. City of Beaumont*, 506 F.3d 895, 900 (9th
12 Cir. 2007).

13 However, bare, conclusory allegations, including legal allegations couched as
14 factual, are not entitled to be assumed to be true. *Twombly*, 550 U.S. at 555. “[T]he tenet
15 that a court must accept as true all of the allegations contained in a complaint is
16 inapplicable to legal conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “While
17 legal conclusions can provide the framework of a complaint, they must be supported by
18 factual allegations.” *Id.* at 679. Thus, this court considers the conclusory statements in a
19 complaint pursuant to their factual context.

20 To be plausible on its face, a claim must be more than merely possible or
21 conceivable. “[W]here the well-pleaded facts do not permit the court to infer more than the
22 mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—that the
23 pleader is entitled to relief.” *Id.* (citing Fed. R. Civ. P. 8(a)(2)). Rather, the factual
24 allegations must push the claim “across the line from conceivable to plausible.” *Twombly*,
25 550 U.S. at 570. Thus, allegations that are consistent with a claim, but that are more likely
26 explained by lawful behavior, do not plausibly establish a claim. *Id.* at 567.

1 In alleging fraud, a plaintiff must also satisfy the requirements of Rule 9(b), requiring
 2 that the plaintiff “must state with particularity the circumstances constituting fraud or
 3 mistake.” “Rule 9(b) demands that the circumstances constituting the alleged fraud ‘be
 4 specific enough to give defendants notice of the particular misconduct . . . so that they can
 5 defend against the charge and not just deny that they have done anything wrong.’” *Kearns*
 6 *v. Ford Motor Co.*, 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *Bly-Magee v. California*,
 7 236 F.3d 1014, 1019 (9th Cir. 2001)). In short, the plaintiff must plead facts showing “‘the
 8 who, what, when, where and how of the misconduct charged.’” *Id.*, (quoting *Vess v. Ciba-*
 9 *Geigy Corp, USA*, 317 F.3d 1097, 1106 (9th Cir. 2003)).

10 Finally, as this matter is also governed by the Reform Act, the plaintiffs must (a)
 11 “specify each statement alleged to have been misleading [and] the reason or reasons why
 12 the statement is misleading,” (b) “state with particularity all facts on which [a] belief is
 13 formed” regarding the statement or omission, and (c) “state with particularity facts giving
 14 rise to a strong inference that the defendant acted with the required state of mind.” 15
 15 U.S.C. §78u-4(b).

16 Background

17 As both parties are familiar with the Amended Complaint, and as the complaint
 18 comprises 93 pages and 219 numbered paragraphs, the Court will endeavor only to
 19 provide a very broad summary of the plaintiff’s theories and allegations.

20 “Generic leucovorin” is a drug used in the chemo-therapy treatment of colorectal
 21 cancer, and consists of a mixture of equal parts of the levo-isomer and dextro-isomer of
 22 leucovorin. Only the levo-isomer of leucovorin is considered pharmacologically active.

23 Fusilev is, essentially, a purified form of leucovorin consisting solely of the active
 24 levo-isomer and is marketed solely by Spectrum. Fusilev costs four times as much as
 25 generic leucovorin.

1 A 1997 study comparing treatments using identical doses (but not equipotent doses)
2 of levo-isomer leucovorin and generic leucovorin in the treatment of colorectal cancer did
3 not identify any statistically significant differences in therapeutic effectiveness or adverse
4 reactions.

5 In 2008, a shortage of generic leucovorin developed. In April 2011, the FDA
6 approved Fusilev for use in the treatment of colon cancer and Spectrum began marketing
7 Fusilev for the treatment of colon cancer. In the context of the ongoing shortage of generic
8 leucovorin, Fusilev sales rose quickly and soon became Spectrum's primary source of
9 revenue.

10 The defendants paid particular attention to the Fusilev business and had access to
11 data that would inform the defendants of the status of Fusilev sales and end-user demand.
12 As early as the summer of 2012, Spectrum's sales personnel became aware that end-user
13 demand for Fusilev was declining, and that this was in response to increased availability of
14 generic leucovorin. The defendants knew that end-user demand was falling but artificially
15 maintained sales.

16 As the shortage of generic leucovorin had had a significant positive impact on
17 Fusilev revenue, market analysts specifically questioned Spectrum whether the recent
18 increased availability of generic leucovorin would negatively impact Fusilev revenue. The
19 defendants misleadingly asserted (and supported through various statements) that the
20 increased availability of generic leucovorin would not have a negative impact, but that
21 Fusilev revenue would continue to grow.

22 The defendants continued making statements maintaining this position through
23 February 2013. In March 2013, however, Spectrum issued a press release to state a
24 revised expectation that revenue from Fusilev would significantly and quickly drop (upward
25 of a 78% decline in the first quarter of 2013, and more than a 50% decline for 2013). In
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1 response to this press release, Spectrum's stock dropped by more than 37% on heavy
2 training.

3 Analysis

4 The defendants argue that the plaintiff failed to identify the specific statements
5 alleged to be false or misleading. The Court disagrees. While the plaintiff did block quote
6 statements made by defendants, the context of the quotes and following paragraphs
7 sufficiently indicates that the plaintiff is alleging that only certain of the statements recited in
8 each block quote are false or misleading. Further, as between the block quotes and the
9 following paragraphs, the plaintiffs have specifically identified the statements within the
10 block quotes that it alleges are false or misleading.¹

11 The defendants argue that their statements are protected by the "safe harbor" of
12 "forward-looking statements." As recognized by the defendants, "if a forward-looking
13 statement is identified as such and accompanied *by meaningful cautionary statements*,
14 then the state of mind of the individual making the statement is irrelevant, and the
15 statement is not actionable regardless of the plaintiff's showing of scienter." *In re Cutera*
16 *Sec. Litig.*, 610 F.3d 1103, 1112 (9th Cir. 2010). The plaintiff's underlying allegation is that
17 the defendants knew that end-user demand was declining in response to the increased
18 availability of generic leucovorin. In the context of this alleged knowledge, the defendants
19 have not established, as a matter of law, that their forward-looking statements were
20 accompanied by meaningful cautionary statements. Cautionary language identifying
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23 ¹ The Court further disagrees that the Amended Complaint is a "puzzle-
24 pleading" that forces one to guess at which statements are alleged to be false or
25 misleading. While Rule 8 requires a concise pleading, the requirements of Rule 9 and the
26 Reform Act impose a countervailing obligation of detailed and extensive allegations. The
Amended Complaint sufficiently balances these competing interests, and in the opinion of
this Court provides sufficient notice to the defendants of the statements alleged to be
misleading or false and the reasons those statements are alleged to be false or misleading.

1 potential adverse events is not meaningful when it conflicts with or fails to reflect current
2 adverse events known to the speaker.

3 The defendants' argument that none of their statements were false or misleading
4 when made fails. "Disclosure is required . . . only when necessary 'to make . . . statements
5 made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives, Inc. v. Siracusano*, 131 S.Ct. 1309, 1321 (2011) (quoting 17 C.F.R.
6 § 240.10b). "Some statements, although literally accurate, can become, through their
7 context and manner of presentation, devices which mislead investors. For that reason, the
8 disclosure required by the securities laws is not measured by literal truth, but by the ability
9 of the material to accurately inform rather than mislead prospective buyers." *Miller v.*
10 *Thane Int'l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008). Regardless of whether the defendants
11 had a "general obligation" of disclosure regarding end-user demand, bulk pricing, or that
12 sales continued to be made to distributors despite growing inventories, the plaintiff has
13 alleged that the defendants made statements that, in light of circumstances, required a
14 further disclosure so that such statements would not be misleading. Similarly, the
15 defendants' efforts to argue that the statements are accurate fails because the plaintiff has
16 alleged sufficient facts to establish that the statements, even if literally true when
17 considered in isolation, were delivered in a context and manner that would mislead rather
18 than accurately inform prospective buyers.

19 The plaintiff has also adequately pled scienter. To plead scienter, a plaintiff must
20 "state with particularity facts giving rise to a strong inference that defendants acted with the
21 intent to deceive or with deliberate recklessness as to the possibility of misleading
22 investors." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 987 (9th Cir. 2008). "The
23 inference that the defendant acted with scienter need not be irrefutable, i.e., of the
24 'smoking-gun' genre, or even the 'most plausible of competing inferences.'" *Tellabs Inc. v.*
25 *Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). A complaint survives if, "[w]hen
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1 the allegations are accepted as true and taken collectively,” a reasonable person would
2 “deem the inference of scienter at least as strong as any opposing inference.” *Id.* at 326.
3 Although an evaluation of whether a “strong inference” of scienter has been adequately
4 pled “must take into account plausible opposing inferences,” the only “opposing” inferences
5 to be considered are those that “one could draw from the facts alleged.” *Id.* at 323-24. The
6 complaint alleges sufficient facts that, when considered as a whole, create a strong
7 inference that the defendants acted with an intent to deceive or, at a minimum, with a
8 deliberate recklessness as to the possibility of misleading investors. The plaintiff has
9 alleged facts showing the importance of Fusilev sales to Spectrum’s business; that the
10 defendants knew that the impact of the return of generic leucovorin supplies on Fusilev
11 end-user demand was of concern to investors; that the defendants had access to sources
12 of information allowing them to ascertain that the Fusilev end-user demand was declining
13 as generic leucovorin became more readily available; and that the actual, and negative
14 impact, was noticed by Spectrum employees. The allegations permit a strong inference
15 that the defendants could not remain unaware of the negative impact and decline of end-
16 user demand as it was occurring. In addition, the plaintiff has alleged facts showing that
17 Shrotriya, in defending his assertion that end-user demand was stable, prefaced such
18 assertion by stating “[w]hat we watch and monitor very closely is underlying end-user
19 demand.” Having sufficiently alleged that monitoring end-user demand would have
20 revealed the decline of end-user demand, the allegation permits an inference of scienter.
21 Further, Shrotriya’s sale of stocks during the Class Period (in contrast to his lack of
22 transactions in comparable periods before and after) also raise an inference of scienter.

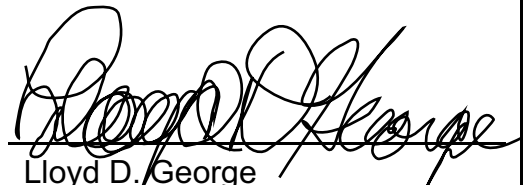
23 Finally, the Court finds that the plaintiff has alleged loss causation. The loss event is
24 clearly identified as the significant drop in stock price immediately following the defendants’
25 March 12, 2013, announcement that Fusilev sales would drop significantly in response to
26 the “recent stabilization” (ie, increased availability) of the generic leucovorin market. This

1 event occurred subsequent to defendants' conduct and representations to mislead
2 investors over the prior months that end-user demand for Fusilev was not and would not
3 decline with increasing availability of generic leucovorin.

4 Accordingly, for good cause shown,

5 THE COURT **ORDERS** that Defendants' Motion to Dismiss (#108) is DENIED.

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7 DATED this 26 day of March, 2015.

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10 Lloyd D. George
11 United States District Judge
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